REMARKS

Claims 1-79 are pending in the application. Claims 1, 2, 27-40 and 71-79 stand rejected pursuant to 35 U.S.C. § 112, first paragraph. Claims 71-73 stand rejected pursuant to 35 U.S.C. § 112, second paragraph. Applicants respectfully traverse the rejections.

Claims 1, 2, 27-40 and 71-79 have been amended to delete the term "prodrug". Accordingly, the rejection of claims 1 and 27, and dependent claims 2, 28-40, and 71-79, has been rendered moot in light of the amendments.

Regarding claims 76-79, the Examiner contends that the specification fails to describe the definition of possible additional active ingredients. Applicants respectfully submit that the guidance provided on page 5, line 9, through page 6, line 13, describes that the compound of the invention can be favorably provided with another analgesic compound to provide pain relief and treatment of disorders ameliorated by controlling neurotransmitter release. The specification details characteristics of classes of suitable compounds, *e.g.* non-steroid anti-inflammatory agents, opioids, tricyclic antidepressants, and anticonvulsants, as well as providing specific, individual examples of suitable additional active ingredients. Accordingly, applicants respectfully request the rejection be withdrawn.

The Examiner finds that claims 71-73 are vague and indefinite in view of the guidance provided regarding the diseases capable of being ameliorated by the administration of the claimed compounds. Applicants respectfully traverse the rejection.

Claim 71 relates to a composition comprising a compound of formula I in a pharmaceutically acceptable carrier. There are no claim elements directed to a disease state. Applicants respectfully submit that amended claim 71 is patentable in accordance with 35 U.S.C. § 112, second paragraph and request the rejection be withdrawn.

Claims 72 and 73 have been amended to include specific disorders to further clarify the claimed methods. As amended, claims 72 relates to a method for selectively controlling neurotransmitter release in a mammal in need of treatment for Alzheimer's disease, Parkinson's disease, attention deficit hyperactivity disorder, depression, pain,

nicotinic withdrawal syndrome, Tourette's syndrome, and schizophrenia. Claim 73 relates to treating a disorder in a host mammal in need of treatment for the same conditions. Applicants respectfully submit that the administration of compounds useful for selectively controlling neurotransmitter release can provide treatment for the named conditions.

Applicants amend claim 30 to include the compound (cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane and add new claims 80 and 81 relating to a pharmaceutical composition containing and a method of using the same. Applicants respectfully submit that such amendment of the claims adds no new matter in that the claimed subject matter related to (cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane is described in the specification, as filed, on at least pages 16, line 30, through, page 17, line 3, as well as the original claims and Schemes.

For the convenience of the Examiner, a complete set of the claims is provided herewith in accordance with the guidelines for the revised format of amendments in view of 37 C.F.R. § 1.121. Applicants reserve the right to file divisional applications on any non-pending or non-elected subject matter.

Should the Examiner have questions or concerns regarding the foregoing, she is respectfully invited to contact the undersigned by telephone at the phone number provided below.

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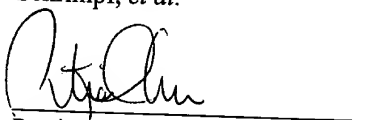
Respectfully submitted,
Schrimpf, *et al.*



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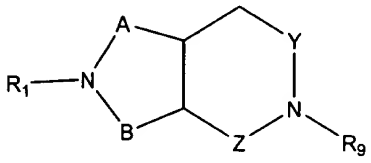
CLAIM AMENDMENTS

Claim 1. (Currently Amended) A compound of formula I



I,

or pharmaceutically acceptable salts ~~and prodrugs~~ thereof, wherein

A is selected from the group consisting of a covalent bond, CH_2, CH_2CH_2, and $CH_2CH_2CH_2$;

B is selected from the group consisting of CH_2 and CH_2CH_2, provided that when A is $CH_2CH_2CH_2$, then B is CH_2;

Y is selected from the group consisting of a covalent bond, CH_2, and CH_2CH_2;

Z is selected from the group consisting of a covalent bond, CH_2, and CH_2CH_2, provided that when Y is CH_2CH_2, then Z is a covalent bond and further provided that when Z is CH_2CH_2, then Y is a covalent bond;

R_1 is selected from the group consisting of

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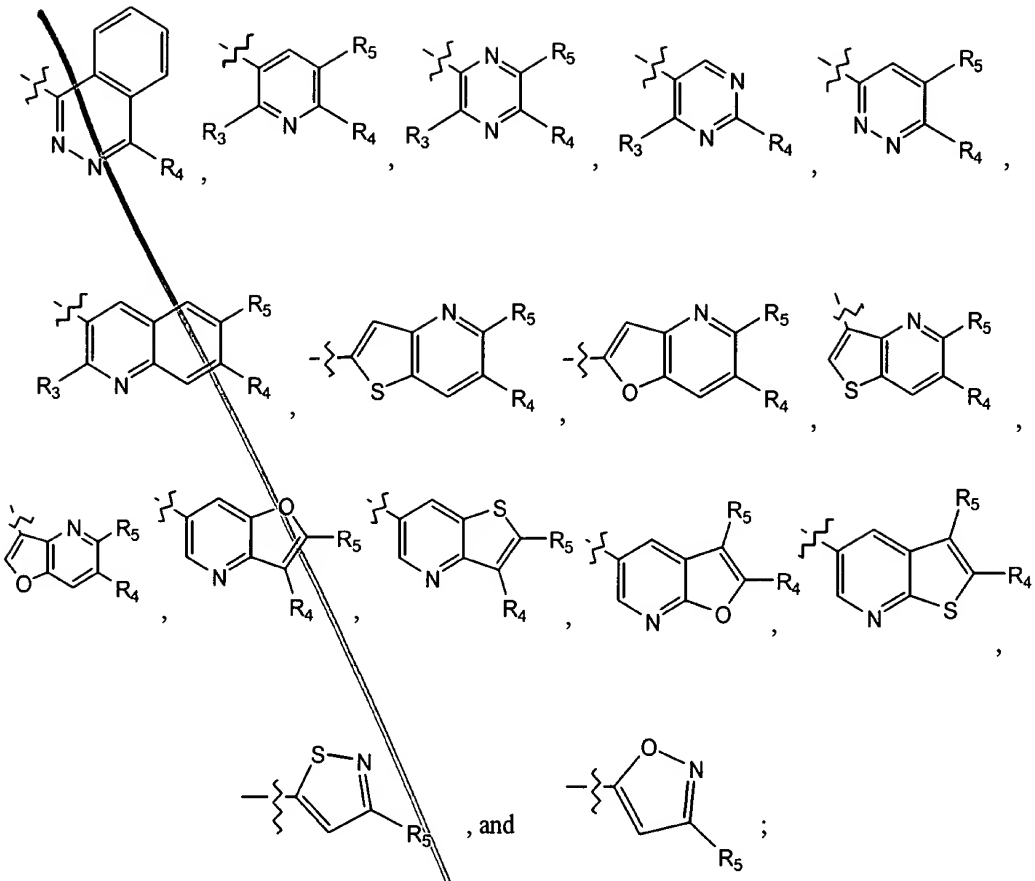


, and ;

R_3 is selected from the group consisting of hydrogen, alkyl, and halogen;

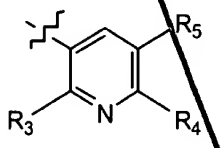
R_4 is selected from the group consisting of hydrogen, alkoxy, alkyl, amino, halogen, and nitro;

R_5 is selected from the group consisting of hydrogen, alkenyl, alkoxy, alkoxyalkoxy, alkoxyalkyl, alkoxycarbonyl, alkoxycarbonylalkyl, alkyl, alkylcarbonyl, alkylcarbonyloxy, alkylthio, alkynyl, amino, aminoalkyl, aminocarbonyl, aminocarbonylalkyl, aminosulfonyl, carboxy, carboxyalkyl, cyano, cyanoalkyl, formyl, formylalkyl, haloalkoxy, haloalkyl, halogen, hydroxy, hydroxyalkyl, mercapto, mercaptoalkyl, nitro, 5-tetrazolyl, $-NR_6S(O)_2R_7$, $-C(NR_6)NR_7R_8$, $-CH_2C(NR_6)NR_7R_8$, $-C(NOR_6)R_7$, $-C(NCN)R_6$, $-C(NNR_6R_7)R_8$, $-S(O)_2OR_6$, and $-S(O)_2R_6$;

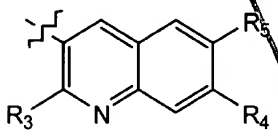
R_6, R_7, and R_8 are independently selected from the group consisting of hydrogen and alkyl; and

R_9 is selected from the group consisting of hydrogen, alkoxycarbonyl, alkyl, amino, aminoalkyl, aminocarbonylalkyl, benzyloxycarbonyl, cyanoalkyl, dihydro-3-pyridinylcarbonyl, hydroxy, hydroxyalkyl, and phenoxycarbonyl.

Claim 2. (Original) A compound according to claim 1 wherein R_1 is selected from the group consisting of

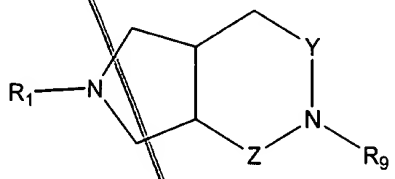


and



Claims 3-26 have been cancelled.

Claim 27. (Currently Amended) A compound according to claim 1 of formula IV:



IV,

or pharmaceutically acceptable salts ~~and prodrugs~~ thereof.

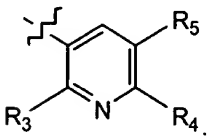
Claim 28. (Original) A compound according to claim 27 wherein Y is a covalent bond and Z is a covalent bond.

Claim 29. (Original) A compound according to claim 27 wherein

Y is a covalent bond;

Z is a covalent bond; and

R_1 is



Claim 30. (Currently Amended) A compound according to claim 29 selected from the group consisting of

(cis)-3-(3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane;

(cis)-3-(6-chloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane;

5-[(1R,5R)-3,6-diazabicyclo[3.2.0]hept-3-yl]nicotinonitrile; ~~and~~

(1R,5R)-3-(6-chloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane~~.~~**; and**

(cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane.

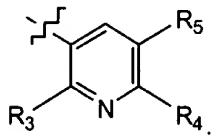
Claim 31. (Original) A compound according to claim 27 wherein Y is CH_2 and Z is a covalent bond.

Claim 32. (Original) A compound according to claim 27 wherein

Y is CH_2;

Z is a covalent bond; and

R_1 is



Claim 33. (Original) A compound according to claim 32 selected from the group consisting of

(cis)-5-(6-chloro-3-pyridinyl)octahydrpyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(6-chloro-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(6-chloro-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5,6-dichloro-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(5,6-dichloro-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(6-chloro-5-methyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(6-chloro-5-methyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5-methoxy-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(5-bromo-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aS,6aS)-5-(5-methoxy-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5-ethynyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5-bromo-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

5-((3aR,6aR)-hexahydropyrrolo[3,4-b]pyrrol-5(1H)-yl)nicotinonitrile;

(3aR,6aR)-5-(6-bromo-5-methoxy-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

5-((3aR,6aR)-hexahydropyrrolo[3,4-b]pyrrol-5(1H)-yl)-2-bromonicotinonitrile;

(3aR,6aR)-5-(5-vinyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5-methyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(6-bromo-5-chloro-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(6-bromo-5-methyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

(3aR,6aR)-5-(5-ethyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

[5-((3aR,6aR)-hexahydropyrrolo[3,4-b]pyrrol-5(1H)-yl)-2-bromo-3-pyridinyl]methanol;

(3aR,6aR)-5-(6-bromo-5-vinyl-3-pyridinyl)octahydropyrrolo[3,4-b]pyrrole;

[5-((3aR,6aR)-hexahydropyrrolo[3,4-b]pyrrol-5(1H)-yl)-2-bromo-3-pyridinyl]acetonitrile; and

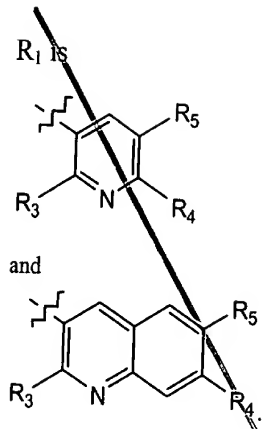
(3aR,6aR)-5-[6-bromo-5-(methoxymethyl)-3-pyridinyl]octahydropyrrolo[3,4-b]pyrrole.

Claim 34. (Original) A compound according to claim 27 wherein Y is a covalent bond and Z is CH_2.

Claim 35. (Original) A compound according to claim 27 wherein

Y is a covalent bond;

Z is CH_2; and



Claim 36. (Original) A compound according to claim 35 selected from the group consisting of

(cis)-2-(3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-methyl-5-(3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(6-chloro-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(6-chloro-3-pyridinyl)-5-methyloctahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(3-quinolinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(5-hydroxy-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(5-methoxy-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(5-ethoxy-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(5-propoxy-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(6-chloro-5-methoxy-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole;

(cis)-2-(6-chloro-5-methyl-3-pyridinyl)octahydropyrrolo[3,4-c]pyrrole; and

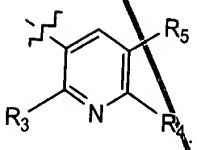
(cis)-2-[5-(2,2,2-trifluoroethoxy)-3-pyridinyl]octahydropyrrolo[3,4-c]pyrrole.

Claim 37. (Original) A compound according to claim 27 wherein Y is CH_2CH_2 and Z is a covalent bond.

Claim 38. (Original) A compound according to claim 27 wherein Y is CH_2CH_2;

Z is a covalent bond; and

R_1 is



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Claim 39. (Original) A compound according to claim 38 selected from the group consisting of

(cis)-6-(6-chloro-3-pyridinyl)octahydro-1H-pyrrolo[3,4-b]pyridine and

A1 (cis)-6-(3-pyridinyl)octahydro-1H-pyrrolo[3,4-b]pyridine.

Claim 40. (Original) A compound according to claim 27 wherein Y is CH_2 and Z is CH_2.

Claims 41-70 have been cancelled.

Claim 71. (Currently Amended) A ~~pharmaceutical~~ composition comprising a ~~therapeutically effective amount of~~ a compound of Claim 1 in combination with a pharmaceutically acceptable carrier.

Claim 72. (Currently Amended) A method for selectively controlling neurotransmitter release in a mammal comprising administering **a therapeutically effective amount of a compound of Claim 1** to a mammal in need of ~~such~~ treatment **for a condition selected from the group consisting of Alzheimer's disease, Parkinson's disease, attention deficit hyperactivity disorder, depression, pain, nicotinic withdrawal syndrome, Tourette's syndrome, and schizophrenia** ~~a therapeutically effective amount of a compound of Claim 1~~.

Claim 73. (Currently Amended) A method of treating a disorder ~~wherein the disorder is ameliorated by controlling neurotransmitter release~~ comprising **administering a therapeutically effective amount of a compound of Claim 1 to** ~~in~~ a host mammal in need of ~~such~~ treatment **for a condition selected from the group consisting of Alzheimer's disease, Parkinson's disease, attention deficit hyperactivity disorder, depression, pain, nicotinic withdrawal syndrome, Tourette's syndrome, and schizophrenia** ~~comprising administering a therapeutically effective amount of a compound of Claim 1~~.

Claims 74 and 75 have been cancelled.

Claim 76. (Original) A method of treating pain in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of Claim 1 in combination with a non-steroid anti-inflammatory agent and a pharmaceutically acceptable carrier.

Claim 77. (Original) A method of treating pain in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of Claim 1 in combination with an opioid and a pharmaceutically acceptable carrier.

Claim 78. (Original) A method of treating pain in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of Claim 1 in combination with a tricyclic antidepressant and a pharmaceutically acceptable carrier.

Claim 79. (Original) A method of treating pain in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of Claim 1 in combination with an anticonvulsant and a pharmaceutically acceptable carrier.

Claim 80. (New Claim) A composition comprising administering (cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane in combination with a pharmaceutically acceptable carrier.

Claim 81. (New Claim) A method for treating a disorder comprising administering a therapeutically effective amount of (cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane to a mammal in need of treatment for a condition selected from the group consisting of Alzheimer's disease, Parkinson's disease, attention deficit hyperactivity disorder, depression, pain, nicotinic withdrawal syndrome, Tourette's syndrome, and schizophrenia.